

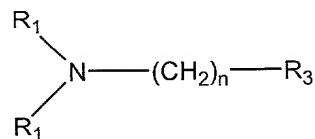
We claim:

1. An assay for detecting the presence of an analyte of interest in a test sample, comprising:

(a) forming a reaction mixture by combining:

- 5 (i) said test sample;
- (ii) a known amount of sensitized particles having immobilized thereon an analyte-specific binding partner; and
- (iii) a known amount of an additive that reduces non-specific aggregation of said particles, wherein said additive is a compound having

10 the formula:



where R_1 and R_2 independently are substituted or unsubstituted alkyl or $-(CH_2)_mOH$;

m is 1-3;

15 R_3 is hydroxy, cyano, substituted or unsubstituted alkyl, $-COOX$, or $-CH(NH_2)Y$;

X is hydrogen or substituted or unsubstituted alkyl;

Y is hydrogen, substituted or unsubstituted amino, or substituted or unsubstituted alkyl; and

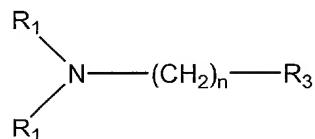
20 n is 0-3;

- (b) incubating the reaction mixture under conditions that allow said particle-immobilized binding partner to bind to said analyte to cause specific aggregation of said particles, wherein said additive is present in an amount sufficient to reduce non-specific particle aggregation; and
- 25 (c) determining the extent of specific aggregation, wherein the extent is proportional to the amount of said analyte in said sample.

2. The assay of claim 1, wherein said additive is present in a concentration ranging from about 0.02M to 0.2M based on the total volume of the reaction mixture.

- 5 3. The assay of claim 1, wherein said additive is selected from the group consisting of triethanolamine, trimethanolamine, N-butylmethanolamine, 3-dimethylamino-2-methylpropyl chloride, N,N-dimethylglycine, N,N-dimethylguanidine, N,N-dimethylglycine ethyl ester, 3-dimethylaminopropionitrile, N,N-diethylacetamide, 1-dimethylamino-2-propylamine.
- 10 4. The assay of claim 3, wherein said additive is N,N-dimethylglycine ethyl ester.
- 15 5. The assay of claim 3, wherein said additive is 3-dimethylamino-2-methylpropyl chloride.
- 20 6. The assay of claim 1, wherein said particles comprise latex particles.
- 25 7. The assay of claim 1, wherein said test sample is selected from the group consisting of whole blood, plasma, serum, saliva, cerebral spinal fluid, urine, amniotic fluid, urine, feces, mucus, cell extracts, and tissue extracts.
- 30 8. The assay of claim 1, wherein said analyte is selected from the group consisting of drugs, antigens, haptens, antibodies, proteins, peptides, amino acids, hormones, steroids, cancer cell markers, tissue cells, viruses, vitamins, nucleic acids, and pesticides.
- 35 9. The assay of claim 1, wherein said binding partner is selected from the group consisting of antigens, antigen fragments, receptors, nucleic acids, and polyclonal antibodies, monoclonal antibodies, and antibody fragments.
- 40 10. An indirect assay for determining the presence of an analyte of interest in a test sample, comprising:
- 45 (a) providing a sample which may contain the analyte of interest;
- 50 (b) providing a known amount of a suspension of sensitized particles having analyte of interest immobilized thereon;
- 55 (c) providing a known amount of an analyte-specific binding partner;

providing an additive that reduces non-specific aggregation of said particles, wherein said additive is a compound having the formula:



where R₁ and R₂ independently are substituted or unsubstituted alkyl or -(CH₂)_mOH;

5 m is 1-3;

R₃ is hydroxy, cyano, substituted or unsubstituted alkyl, -COOX, or -CH(NH₂)Y;

X is hydrogen or substituted or unsubstituted alkyl;

10 Y is hydrogen, substituted or unsubstituted amino, or substituted or unsubstituted alkyl; and

n is 0-3;

- (d) combining said sample with said sensitized particles, said binding partner and said additive under conditions that allow binding between said binding partner and said particle-immobilized analyte to cause specific aggregation of said particles or to said analyte in said sample, wherein said additive is present in an amount sufficient to reduce non-specific particle aggregation; and
- (e) determining the amount of said particle-immobilized analyte that is bound with said binding partner, wherein the amount is inversely proportional to the amount of said analyte in said sample.

20 11. The assay of claim 10, wherein said additive is present in a concentration ranging

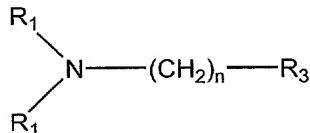
from about 0.02M to 0.2M based on the total volume of the reaction mixture.

12. The assay of claim 10, wherein said additive is selected from the group consisting

25 of triethanolamine, trimethanolamine, N-butyldiethanolamine, 3-dimethylamino-2-methylpropyl chloride, N,N-dimethylglycine, N,N-dimethylguanidine, N,N-dimethylglycine ethyl ester, 3-dimethylaminopropionitrile, N,N-diethylacetamide, 1-dimethylamino-2-propylamine.

13. The assay of claim 12, wherein said additive is N,N-dimethylglycine ethyl ester.

- 40040005 * 120204
- 14. The assay of claim 12, wherein said additive is 3-dimethylamino-2-methylpropyl chloride.
 - 15. The assay of claim 10, wherein said particles comprise latex particles.
 - 16. The assay of claim 10, wherein said test sample is selected from the group consisting of whole blood, plasma, serum, saliva, cerebral spinal fluid, urine, amniotic fluid, urine, feces, mucus, cell extracts, and tissue extracts.
 - 17. The assay of claim 10, wherein step (d) further comprises first mixing said test sample with said binding partner and said additive, and combining the resultant mixture with said sensitized particles.
 - 18. The assay of claim 10, wherein step (d) further comprises first mixing said test sample with said sensitized particles and said additive, and combining the resultant mixture with said binding partner.
 - 19. The assay of claim 10, wherein said analyte is selected from the group consisting of drugs, antigens, haptens, antibodies, proteins, peptides, amino acids, hormones, steroids, cancer cell markers, tissue cells, viruses, vitamins, nucleic acids, and pesticides.
 - 20. The assay of claim 10, wherein said binding partner is selected from the group consisting of antigens, antigen fragments, receptors, nucleic acids, and polyclonal antibodies, monoclonal antibodies, and antibody fragments.
 - 21. A kit for assaying an analyte in a test sample, said kit comprising first and second container means, said first container means containing sensitized particles having an analyte-specific binding partner immobilized thereon, said second container means containing a sufficient amount of an additive to reduce non-specific aggregation of said particles, wherein said additive is a compound having the formula:



where R_1 and R_2 independently are substituted or unsubstituted alkyl or -

$(CH_2)_mOH$;

m is 1-3;

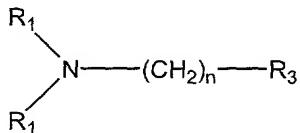
R_3 is hydroxy, cyano, substituted or unsubstituted alkyl, $-COOX$, or $-CH(NH_2)Y$;

X is hydrogen or substituted or unsubstituted alkyl;

Y is hydrogen, substituted or unsubstituted amino, or substituted or unsubstituted alkyl; and

n is 0-3.

- 5 22. The kit of claim 21, wherein said additive is N,N-dimethylglycine ethyl ester.
- 23. The kit of claim 21, wherein said additive is 3-dimethylamino-2-methylpropyl chloride.
- 24. The kit of claim 21, wherein said additive is present in a concentration ranging from about 0.02M to 0.2M based on the total volume of the reaction mixture.
- 10 25. The kit of claim 21, wherein said test sample is selected from the group consisting of whole blood, plasma, serum, saliva, cerebral spinal fluid, urine, amniotic fluid, urine, feces, mucus, cell extracts and tissue extracts.
- 26. The kit of claim 21, wherein said analyte is selected from the group consisting of drugs, antigens, haptens, antibodies, proteins, peptides, amino acids, hormones, steroids, cancer cell markers, tissue cells, viruses, vitamins, nucleic acids, and pesticides.
- 15 27. The kit of claim 21, wherein said binding partner is selected from the group consisting of antigens, antigen fragments, receptors, nucleic acids, and polyclonal antibodies, monoclonal antibodies, and antibody fragments .
- 20 28. The kit of claim 21, wherein said particles are latex particles.
- 29. A composition useful for assaying an analyte of interest, said composition comprising microparticles having an analyte-specific binding partner immobilized thereon, and a sufficient amount of an additive to reduce non-specific aggregation of said particles, wherein said additive is a compound having the formula:



25

where R₁ and R₂ independently are substituted or unsubstituted alkyl or -

(CH₂)_mOH;

m is 1-3;

R₃ is hydroxy, cyano, substituted or unsubstituted alkyl, -COOX, or -CH(NH₂)Y;

30

X is hydrogen or substituted or unsubstituted alkyl;

- Y is hydrogen, substituted or unsubstituted amino, or substituted or unsubstituted alkyl; and
n is 0-3.
30. The composition of claim 29, wherein said additive is selected from the group consisting of triethanolamine, trimethanolamine, N-butyldiethanolamine, 3-dimethylamino-2-methylpropyl chloride, N,N-dimethylglycine, N,N-dimethylguanidine, N,N-dimethylglycine ethyl ester, 3-dimethylaminopropionitrile, N,N-diethylacetamide, 1-dimethylamino-2-propylamine.
- 10 31. The composition of claim 30, wherein said additive is N,N-dimethylglycine ethyl ester.
32. The composition of claim 30, wherein said additive is 3-dimethylamino-2-methylpropyl chloride.
33. The composition of claim 29, wherein said particles are latex particles.
- 15 34. The composition of claim 29, wherein said analyte is selected from the group consisting of drugs, antigens, haptens, antibodies, proteins, peptides, amino acids, hormones, steroids, cancer cell markers, tissue cells, viruses, vitamins, nucleic acids, and pesticides.
- 20 35. The composition of claim 27, wherein said binding partner is selected from the group consisting of antigens, antigen fragments, receptors, nucleic acids, and polyclonal antibodies, monoclonal antibodies, and antibody fragments.
36. The composition of claim 27, wherein said additive is present in a concentration ranging from about 0.02M to 0.2M.